



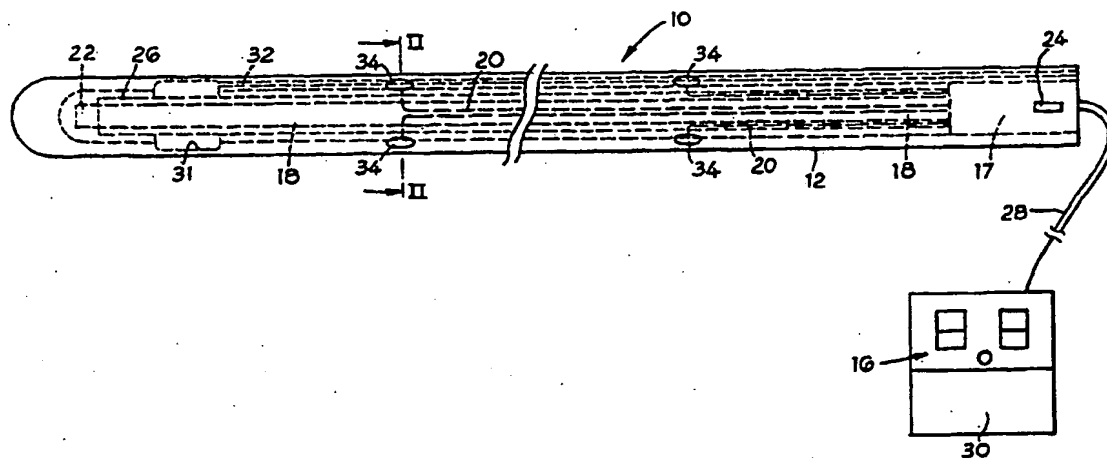
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| <b>(21) International Application Number:</b> PCT/GB96/02296<br><b>(22) International Filing Date:</b> 20 September 1996 (20.09.96)<br><b>(30) Priority Data:</b><br>9519194.6 20 September 1995 (20.09.95) GB<br><b>(71) Applicant (for all designated States except US):</b> UNIVERSITY OF WALES COLLEGE OF MEDICINE [GB/GB]; Heath Park, Cardiff CF4 4XN (GB).<br><b>(72) Inventors; and</b><br><b>(75) Inventors/Applicants (for US only):</b> YOUNG, Howard, Leslie [GB/GB]; 56 Cheriton Drive, Thomhill, Cardiff CF4 5DF (GB); LOWNDES, Richard, Herbert [GB/GB]; Pelvic Floor and G.I. Physiology Unit, West Norwich Hospital, Bowthorpe Road, Norwich NR2 3TU (GB).<br><b>(74) Agents:</b> NEWELL, William, Joseph; Wynne-Jones, Laine & James, 22 Rodney Road, Cheltenham, Gloucestershire GL50 1JJ (GB) et al. |           | <b>(81) Designated States:</b> AU, CA, GB, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).<br><b>Published</b><br><i>With international search report.</i><br><i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> |

**(54) Title:** ANORECTAL ANGLE MEASUREMENT**(57) Abstract**

Apparatus (10) for measuring the anorectal angle comprises an outer rubber-like sheath (12), which may be a suitably modified catheter, within which is disposed an elongate angular deflection detector (14) which provides on display (16) a read-out of the angular deflection of the apparatus. The sheath (12) may include pressure ports with associated pressure lines back to the proximal end of the sheath to allow the pressure to be read at different points along the anal canal.

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### ANORECTAL ANGLE MEASUREMENT

This invention relates to apparatus and methods for measuring the anorectal angle and more generally to apparatus and methods for measuring, monitoring or observing the local anatomy or selected parameters in the anal canal and/or rectum.

Measurement of the anorectal angle (the angle of the anus relative to the rectum) is part of the investigations undertaken to determine the functionality of the anal canal and rectum in patients suffering defecatory disorders. The passage of stools is controlled by a muscular sling which controls the anorectal angle, between an acute angle (closed) and an obtuse angle (open). Lack of proper control can lead to constipation or faecal incontinence. In addition to anorectal angle, the manometric pressure at various points in the rectum and anal canal may be detected, and electro-myological readings may be taken to determine muscle activity.

Generally, the measurement of the anorectal angle has been performed by inserting into the rectum of the patient a radiological contrast medium which has the consistency of a soft stool, to simulate a soft faecal motion. The patient then sits on a radiolucent toilet and is screened radiologically whilst defecating. The difference between the angle of the rectum before and during defecation provides some indication as to whether there may be a functional disorder of the anorectum in patients who have

problems in defecating. This procedure is referred to as a defecating proctogram and is unpleasant for the patient, invasive (requiring exposure to radiation) and many Radiological Units will not or cannot perform the procedure.

5 The procedure also of course requires special equipment and a skilled radiologist to observe and interpret the results.

A need therefore exists for an apparatus and method for use in monitoring the anal canal and/or rectum, for example for measuring anorectal angle which, alleviates at least  
10 some of the above problems, allowing the measurement to be carried out more widely.

Accordingly, in one aspect, this invention provides a method for use in monitoring the anal canal and/or rectum of a patient, which comprises inserting through the anus into  
15 the rectum an elongate flexible element and measuring or observing the angular deflection of said flexible element, and/or the contour adopted thereby.

Preferably, said angular deflection is measured in a single plane, for example the horizontal plane if the  
20 patient is lying on his or her side.

Preferably the change of said angular deflection is measured during a simulated defecatory process.

Preferably, said angular deflection is measured using a sensor associated with said elongate flexible element.

25 Thus in preferred embodiments of this invention, the anorectal angle may be measured without requiring exposure to radiation and without requiring the patient to defecate.

In another aspect, this invention provides apparatus

for use in monitoring the anal canal and/or rectum of a patient, which apparatus comprises an elongate flexible element designed to be introduced via the anus into the rectum and having associated therewith angular deflection  
5 detecting means for detecting the angular deflection thereof and/or the contour adopted by said flexible element.

Preferably, said angular deflection detecting means comprises an elongate flexible core element and sensor means responsive to longitudinal strain disposed along opposed  
10 sides of the core element to determine angular deflection between spaced regions thereof. In one embodiment, the sensor means comprise respective elongate strain gauges extending along substantially the whole length of the elongate flexible core element at circumferentially spaced  
15 locations.

Preferably said elongate flexible element comprises a rubber or rubber-like outer sheath within which is disposed said angular deflection detecting means.

Preferably, said outer sheath includes an inflatable region in the distal position thereof, and whereby said  
20 region may be inflated in use to stimulate the rectum.

Preferably, said apparatus includes pressure detecting means for determining in use the pressure acting in the rectum or adjacent the anus. The pressure detecting means  
25 may comprise one or more pressure sensors located in the outer sheath or pressure ports disposed in the outer sheath leading to one or more associated sensors.

In this way, a single instrument may be provided which

provides a reading of anorectal angle and manometric pressure, and so a 3-D pressure map of pressures within the anorectal region may be constructed.

In a further aspect, this invention provides use of the apparatus as defined as a bio-feedback sensor for training patients with defecatory disorders.

Whilst the invention has been described above, it extends to any inventive combination of features set out above or in the following description.

The invention may be performed in a various ways and an embodiment thereof will now be described in detail, reference being made to the accompanying drawings in which:-

Figure 1 is a schematic side view of apparatus in accordance with this invention;

Figure 2 is a cross sectional view on an enlarged scale of the apparatus of Figure 1, and

Figure 3 is a schematic view showing the apparatus in use.

The apparatus 10 for measuring anorectal angle comprises an outer rubber-like sheath 12, which may be a suitably modified catheter, within which is disposed an elongate angular deflection detector 14 which provides on display 16 a read-out of the angular deflection of the apparatus.

Referring to Figures 1 and 2, the angular deflection detector 14 comprises an anchorage or "fixed" end 17 from which extends a core element 18 of flexible wire or cable and four strain gauge wires 20 extending along the length of

the core and equispaced at 90° around the core, the whole being covered in thin plastics cover 21 (see Figure 2). Such a detector is obtainable from Penny and Giles Limited, Blackwood, Gwent, U.K.

5       The strains experienced by the strain gauge wires 20 are calculated to determine the total strain acting along the whole core on all four sides, thereby to determine the angular deflection between the tip 22 and the anchorage 17. In this particular example, only deflections in the plane of  
10 the section shown in Figure 3 are monitored. The apparatus includes a mark 24 on the outer sheath to ensure that the instrument is used in the correct orientation. Also, as the accuracy of this particular sensor will be degraded if the angular deflection detector 14 is twisted, the apparatus  
15 includes thin flexible strips 26 to either side of the detector to ensure that flexing of the apparatus is confined to the single plane only. From the anchorage 17 the signals are fed by a cable 28 to a processor 30 which drives the display 16. The output is also available to interface with  
20 a suitable PC/software package (not shown) to allow the output from the instrument to be sampled, correlated and/or combined with data from the other sensors for further processing as required.

25       The outer sheath 12 has a central bore in which the deflection detector 14 and strips 26 are snugly located, and the sheath 12 is bonded to the detector anchorage 17. The sheath induces an inflatable balloon chamber 31 at its distal end, fed by a line 32 which runs back to the proximal

end of the device. Likewise eight pressure sample points 34 are located along the extension of the sheath and respective passages run back to the distal end.

In use, the apparatus is inserted into the anus of a patient with the mark 24 aligned with the anterior plane of the patient and pushed in until the distal end is well into the patient's rectum, as seen in Figure 3. Measurements of angle and pressure may be taken. The balloon 31 may be inflated to stimulate defecation or the patient may be asked to push, and the corresponding change in angle measured.

The apparatus gives a quick read out which does not require interpretation to determine the actual angle, and so a numerical score can be given easily. There is minimal invasion of patient privacy compared to the defecating proctogram.

The apparatus is especially suited to bio-feedback, as a patient may be given the apparatus and instructed to practice regularly to obtain a particular angle on the display. In this way, the patient may relearn the appropriate response which may have been lost previously.



CLAIMS

1. A method for use in monitoring the anal canal and/or rectum of a patient, which method comprises inserting through the anus into the rectum an elongate flexible element and measuring or observing the angular deflection of said flexible element and/or the contour adopted thereby.
2. A method according to Claim 1, wherein said angular deflection is measured in a single plane.
3. A method according to Claim 1 or Claim 2, wherein the change of said angular deflection is measured during a simulated defacatory process.
4. A method according to any preceding Claim wherein said angular deflection is measured using a sensor associated with said elongate flexible element.
5. A method according to any preceding Claim, which further includes monitoring the pressure at one or more points in the anal canal and/or rectum using one or more sensor means provided on said elongate flexible element.
6. Apparatus for use in monitoring the anal canal or rectum of a patient, which apparatus comprises an elongate flexible element designed to be introduced via the anus into the rectum and having associated therewith angular deflection detecting means for detecting angular deflection thereof.
7. Apparatus according to Claim 6, wherein said angular deflection detecting means comprises an elongate flexible core element and sensor means responsive to longitudinal

strain along opposed sides of the core element to determine angular deflection between spaced regions thereof.

8. Apparatus according to Claim 7, wherein the sensor means comprise respective elongate strain gauges extending  
5 along substantially the whole length of the elongate flexible core element at radially spaced locations.

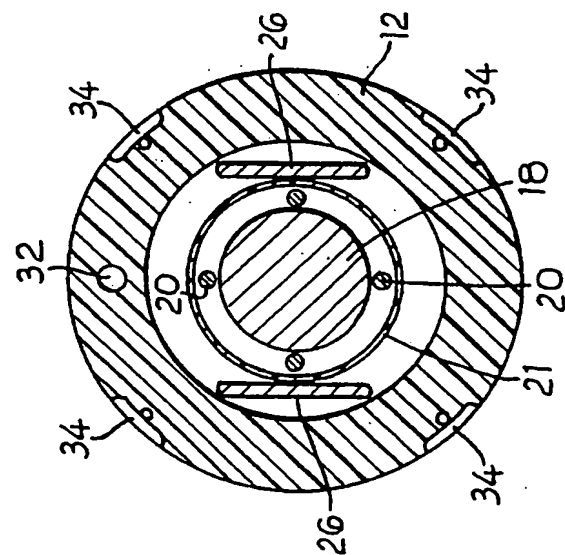
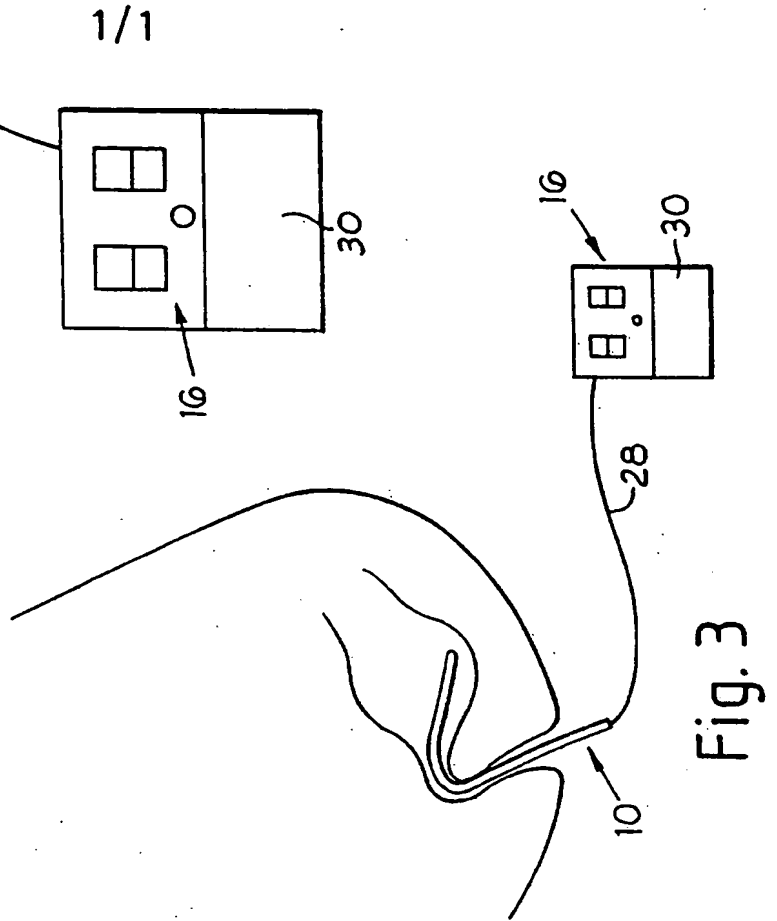
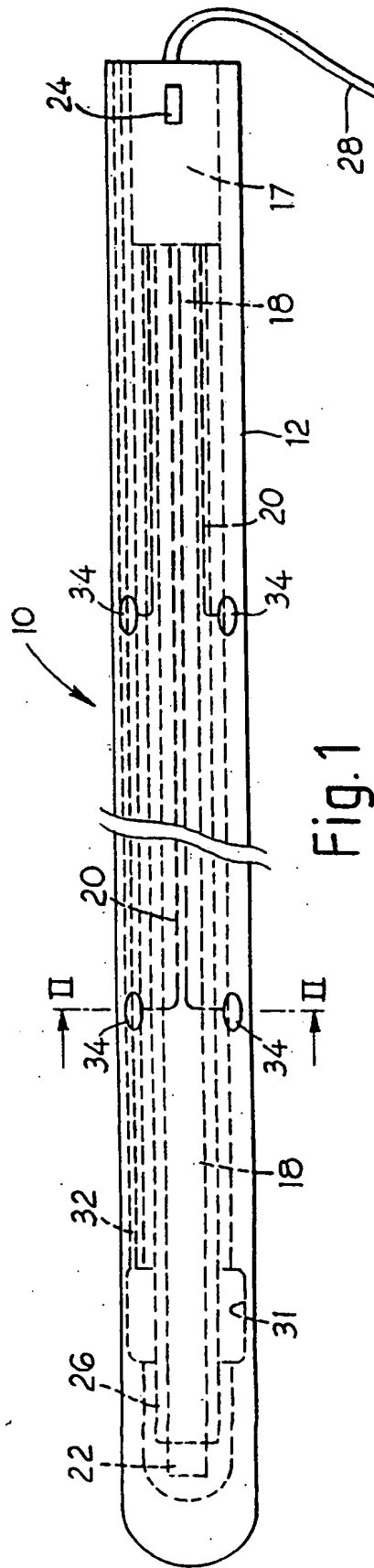
9. Apparatus according to any of Claims 6 to 8, wherein said elongate flexible element comprises a rubber or rubber-like outer sheath within which is disposed said angular  
10 deflection detecting means.

10. Apparatus according to any of Claims 6 to 9, wherein said outer sheath includes an inflatable region in the distal position thereof, and whereby said region may be inflated in use to stimulate the rectum.

15 11. Apparatus according to any of Claims 6 to 10, wherein said apparatus includes pressure detecting means for determining in use the pressure acting in the rectum or adjacent the anus.

12. Apparatus according to Claim 11, wherein the pressure  
20 detecting means comprises one or more pressure sensors located in the outer sheath or pressure ports disposed in the outer sheath leading to one or more associated sensors.

13. A bio-feedback sensor for training a patient with a defacatory disorder, including an elongate flexible element  
25 designed to be introduced via the anus into the rectum and having associated therewith angular deflection detecting means for detecting angular deflection thereof.



# INTERNATIONAL SEARCH REPORT

Intern. Application No  
PCT/GB 96/02296

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61B5/03 A63B23/20

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61B A63B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
| A          | US,A,4 687 002 (C.J.LAHR) 18 August 1987<br>see column 3, line 61 - column 6, line 57;<br>tables 1-6  | 1,6                   |
| A          | US,A,4 873 990 (H.K.HOLMES ET AL) 17<br>October 1989<br>see column 4, line 58 - column 5, line 26<br>see column 4, line 15 - line 23; tables<br>1-5 | 1,8                   |
| A          | US,A,4 366 810 (C.A.SLANETZ,JR) 4 January<br>1983<br>see column 6, line 64 - column 8, line 15;<br>tables 5-7                                       | 5,11,12               |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

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| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)     | Publication<br>date  |
|---|---------------------|--------------------------------|----------------------|
| US-A-4687002                              | 18-08-87            | US-A- 4739767<br>US-A- 5005586 | 26-04-88<br>09-04-91 |
| US-A-4873990                              | 17-10-89            | NONE                           |                      |
| US-A-4366810                              | 04-01-83            | US-A- 4469091                  | 04-09-84             |

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